

EXPERT ADVICE

How to Protect Your Intellectual Property as a Biotech Startup

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Biotechs always start with great scientific ideas, but if you can't protect them, you can't see them through to execution. Companies need to start developing long-term intellectual property strategies almost as early as they are devising the ideas that need protecting.

Experts say that the right intellectual property (IP) strategy for a new biotech depends on the source IP, the timing of the discoveries, the potential applications of the technology, and how creative the company can be within the competitive landscape.

Broad to narrow

“At the very beginning, try to understand the promise and breadth of a particular idea,” says Leda Trivinos, Partner at US Life Sciences VC Flagship Pioneering, who focuses on IP protection. Flagship's portfolio includes [messenger RNA company](#) Moderna Therapeutics and three

biotechs that have had their initial public offerings (IPOs) in the past year: Foghorn Therapeutics, Sigilon Therapeutics, and Sana Biotechnology.

Flagship's approach to company formation means foundational IP is developed in-house by researchers and entrepreneurs with experience developing an idea with commercial potential. Carving out an IP niche is more straightforward, Trivinos says, when there's less 'prior art' — evidence that an invention is already known.

A typical approach is to start patenting for broad applications, then get more specific through subsequent patents. A company can get into IP trouble, for example, if it patents a single molecule but later finds related molecules with similar functions — “*you can't work backwards,*” says Trivinos.

While this applies to all companies, it is particularly relevant to those focused on developing technology platforms. “*If you're a platform company, you need to occupy the space,*” says Jacob Sherkow, professor of law at the University of Illinois at Urbana-Champaign. “*You differentiate yourself by demonstrating the breadth of your technology and the expansiveness of your creativity*” in finding different applications.

Moving from broad to narrow leaves the door open for building on a patent, says Sherkow. That approach is important for additional protection, and may even be worth some restraint on the first patent. “*It's really tough to iterate on your invention with improvements going forward if you've already disclosed everything that you knew,*” Sherkow added.

But going too broad also has risks, says Mike Stramiello, an associate at the international law firm Paul Hastings LLP. “*If you end up with claims that are overly broad to the point that they're invalid, that's no protection at all.*”

Thomas Mehrling, CEO of Laevoroc Oncology, a Swiss, privately owned group of companies, says that asset-centric companies can use the ‘onion’ strategy. The core of the onion is a patent protecting a newly invented active pharmaceutical ingredient (API). The next layer could be a formulation enhancing a specific physicochemical property of the API, then one designed to promote a route of administration, then a use patent for a particular indication. *“That will make it very difficult for people to work around,”* he explains.

Navigating crowded spaces

Even in a crowded field, it’s not impossible to carve out a unique niche. For example, the last decade has seen the formation of dozens of microbiome companies. Flagship Pioneering was early to the party, forming Seres Therapeutics in 2012 to develop therapeutics containing communities of microbes to treat diseases related to gut microbiome dysbiosis.

But Flagship has continued to build microbiome biotechs with unique purviews. In 2015 it launched Evelo Biosciences, focused on single-strain therapies rather than a community of microbes, and Kaleido Biosciences, which modulates beneficial gut bacteria. In 2017, it launched Ring Therapeutics to tap commensal viruses from the gut microbiome to design gene therapy delivery vectors. And last year, Flagship merged four proto-companies to form Senda Biosciences, which is developing therapies that inhibit gut microbial digestion of neurology drugs to extend their efficacy.

“We engage very early on with the origination teams so that we can understand the IP landscape,” says Trivinos. Some spaces are just too crowded, but Flagship thinks the differences in technology and therapeutic approach gives each of their companies a different lens in the microbiome space.

Even in a crowded area, patent attorneys can help identify potential issues and line up licensing strategies to prevent trouble down the line, says Stramiello. *“Just because you’re late doesn’t mean you can’t still be innovating,”* he says. But tread carefully, he added. *“Early entrants into a space may think that they’re entitled to some super broad rights.”*

For one asset that had previously been in development, Mehrling says that his company, Laevoroc, had to contend with a lot of prior art – that is, pre-existing information that had been publicly shared and could therefore not be protected.

“It became a very narrow game to find a space where we could fit in.” After scanning the IP landscape, the company began a six-month chemistry campaign to make improvements to the API’s stability, which it then used to apply for a new patent. *“We’re still not sure if this will be granted, but we’re certainly very positive about it.”*

Timing is everything

IP experts can guide the timing of the filing, says Frank Landolt, Chief Counsel for Intellectual Property and Legal for Confo Therapeutics. *“The saying is that you always file too early, except in those cases where you file too late.”* In a competitive field, some companies are pressured to file as quickly as possible, raising questions under patent law about whether they actually had the invention fully in hand when applying.

Landolt was previously VP of Intellectual Property and Legal at Ablynx, later [acquired by Sanofi](#) in 2018 for €3.9B. He was responsible for the biotech’s IP strategy, which helped the company win an IP battle over antibody half-life extension technology with GlaxoSmithKline-backed Domantis.

Stramiello says biotechs should consult a legal expert early to understand what others are doing in their space, creatively guard against design-arounds, and protect the pipeline in the long term.

“There are some companies out there that spend more time invested in thinking about what to name the company than what their overarching intellectual property strategy is,” says Sherkow. He recommends partnering with a legal professional, or someone from a university business development office, as part of the initial conversations about company formation and strategy.

Trivinos explained that by the time some companies realize they need to protect their invention, it’s already too late. The key is to be early and strategic, instead of reactive, she says. *“If you’re doing IP properly, then IP considerations can also guide some of the experimentation. Think from the top-down, rather than the bottom-up.”*

Timing is about more than just when to start. Platform companies in particular should plan to patent throughout the company’s life cycle. *“That kind of continuous look toward IP is needed,”* Sherkow added. This has been particularly evident recently in the sequencing, RNA interference, and genome editing spaces.

That’s less of a concern for single-asset companies. For them, a few strong, valid patents early can be effective, says Sherkow. Especially when resources are limited, this is typically a better approach than peppering the landscape with mediocre ones.

Stramiello agrees. *“You want to build a moat around what you’re doing, but not necessarily a thicket.”*

Know your rights

Many common issues stem from a failure to know the existing IP landscape in a sector. Sherkow says it's not uncommon for someone to develop a patent, then later find an older patent that covers something similar. *"It's really important to do these prior art searches before launching an entire IP strategy."*

Even one's own patents can get tricky when IP was originally developed outside the company. *"Be very careful and thorough in making sure you have rights to IP,"* says Trivinos. If a co-inventor at a university was left off a patent, for example, it could result in headaches — if not litigation — later on.

The same applies to ongoing collaborations with other companies or universities that could result in IP development, Stramiello says. *"It's important for your collaborations to be carefully thought out, and for those agreements to be understood and fully appreciated for what they are from the get-go."*

Patents aren't the only way to protect IP. Trade secrets can stay safe when early-stage companies operate in 'stealth' mode. *"Be careful about what you put out in public if you haven't carefully thought out your patent strategy,"* says Stramiello. Coordination is key, so that internal scientists, external collaborators, stakeholders, and advisors all stay aligned with the strategy.

Regardless of how strong a patent is, some companies may sue in an effort to slow a competitor down, says Landolt. But litigation should always come after negotiation, not the reverse.

Focus on the technology

For those building a company after a career in academia, protecting IP may not come naturally. In fact, the opposite may be true — publishing often makes or breaks academic careers, and scientists are trained to fit conclusions as narrowly as possible to the evidence from a given experiment, says Sherkow.

But the sting of missing out can be a powerful motivator. *“The thing that is upsetting to company founders is when someone else thinks of a new application of their technology. Their response is to say, ‘why didn’t I think of that?’”*

Luckily, the best IP strategy plays to scientists’ strengths — and that’s to have the best technology, says Landolt. In the midst of its legal battle, Landolt told Ablynx’s board not to get distracted. *“Keep focusing on developing the technology, developing the pipeline. At some point this issue with Domantis will be in the rearview mirror.”*

Better science and worse patents will get a company further than the inverse, says Sherkow. *“The best strategies are technical and scientific ones. You want to make sure you have really excellent science. That is the key to all of this.”*